

---

**U. S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
January 22, 2001**

---

## **Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Producer Trace Back (M-I-96-10 Revision #3)**

**TO:** All Regional Food and Drug Directors  
Attn: Regional Milk Specialists

**FROM:** Milk Safety Team, HFS-626

**SUBJECT:** Drug Residue Test Methods for Confirmation of Presumptive Positive  
Results and Producer Trace Back

This revision of this memorandum modifies the subject to reflect the provisions of M-a-86 and adds the Parallux tests and modifies the tables to reflect the performance of the Lactek BL Beta-lactam Milk Screening Kit.

The following tables have been developed by the Center for Veterinary Medicine to demonstrate those screening tests that have been accepted under the requirements of Appendix N to determine whether positive presumptive tanker test results are screening positive (load confirmation). These tables may also be used to determine an appropriate initial producer trace back test to determine those producer(s) on a positive load. Note: Producers found presumptive positive by one of these tests must be tested for confirmation using the same test that was used to determine the presumptive result (see M-a-86 Revised) for the producer.

These tables do not include any additional requirements for testing and are a reference for which tests are appropriate to test samples from producers which have contributed milk to a positive bulk milk pickup tanker.

Copies of this memorandum are enclosed for your distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Rating Officers in your region. This memorandum is also available on the Center for Food Safety and Applied Nutrition World Wide Web site at <http://www.fda.gov> and should be widely distributed to representatives of the milk industry, state veterinarians, state veterinary and pharmacy boards, veterinarian professional organizations, and all other interested parties.

Joseph M. Smucker, Chief  
Milk Safety Team

INITIAL POSITIVE TEST	CONFIRMATORY TEST OPTIONS
<b>Charm <i>B. stearothermophilus</i> Tablet Disk Assay</b>	<p>Charm. <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm SL Beta-lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta-lactam Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta-lactam Test Kit Parallux Beta-lactam Assay</p>
<b>Charm II Tablet Beta-lactam Test (Competitive Assay)</b>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay + Lactek CEF Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm SL Beta-lactam Test Delvotest P 5 Pack + Lactek CEF Beta-Lactam Milk Screening Kit Delvotest P/Delvotest P Mini + Lactek CEF Beta-lactam Milk Screening Kit Delvotest SP/Delvotest SP Mini + Lactek CEF Beta-lactam Milk Screening Kit Delvo-X-Press Beta-lactam Residue Test Kit Penzyme III Test Procedure + Lactek CEF Beta-lactam Milk Screening Kit</p>

	<p>Penzyme Milk Test + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>SNAP Beta-lactam Test Kit</p> <p>Parallux Beta-lactam Assay</p>
<b>Charm II Tablet Beta-lactam Test (Sequential Assay)</b>	<p>Charm B. stearothermophilus Tablet Disk Assay + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test</p> <p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm SL Beta-lactam Test</p> <p>Delvotest P 5 Pack + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvotest P/Delvotest P Mini + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvotest SP/Delvotest SP Mini +Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvo-X-Press Beta-lactam Residue Test Kit</p> <p>Penzyme III Test Procedure + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Penzyme Milk Test + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>SNAP Beta-lactam Test Kit</p> <p>Parallux Beta-lactam Assay</p>
<b>Charm I/Cowside II Beta-lactam Test</b>	<p>Charm B. stearothermophilus Tablet Disk Assay + Lactek CEF</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test</p> <p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm SL Beta-lactam Test</p> <p>Delvotest P 5 Pack + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvotest P/Delvotest P Mini + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvotest SP/Delvotest SP Mini + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvo-X-Press Beta-lactam Residue Test Kit</p> <p>Penzyme III Test Procedure + Lactek CEF Beta-lactam Milk Screening Kit</p>

	<p>Penzyme Milk Test + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>SNAP Beta-lactam Test Kit</p> <p>Parallux Beta-lactam Assay</p>
<b>Charm II Tablet Beta-lactam Test (Quantitative Assay)</b>	<p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test + Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Parallux Beta-lactam Assay</p>
<b>Charm SL Beta-lactam Test</b>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay + Lactek CEF</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test</p> <p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm SL Beta-lactam Test</p> <p>Delvotest P 5 Pack + Lactek CEF Beta-Lactam Milk Screening Kit</p> <p>Delvotest P/Delvotest P Mini + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvotest SP/Delvotest SP Mini + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Delvo-X-Press Beta-lactam Residue Test Kit</p> <p>Penzyme III Test Procedure + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Penzyme Milk Test + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>SNAP Beta-lactam Test Kit</p> <p>Parallux Beta-lactam Assay</p>
<b>Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay)</b>	<p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Charm II Test for Cloxacillin in Milk</p>

	Lactek B-L Beta-lactam Milk Screening Kit Parallux Beta-lactam Assay Parallux Cloxacillin Assay
<b>Charm II Test for Cloxacillin in Milk (Competitive Assay)</b>	Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm II Test for Cloxacillin in Milk Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay) Lactek B-L Beta-lactam Milk Screening Kit Parallux Beta-lactam Assay Parallux Cloxacillin Assay
<b>Charm II Tetracycline Drug Test</b>	Charm II Tetracycline Drug Test
<b>Charm II Sulfa Drug Test</b>	Charm II Sulfa Drug Test
<b>Delvotest P 5 Pack</b>	Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm SL Beta-lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta-lactam Residue Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta-lactam Test Kit Parallux Beta-lactam Assay
<b>Delvotest P/Delvotest P Mini</b>	Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta-lactam Test Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm SL Beta-lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini

	<p>Delvo-X-Press Beta-lactam Residue test Kit  Penzyme III Test Procedure  Penzyme Milk Test  SNAP Beta-lactam Test Kit  Parallux Beta-lactam Assay</p>
<b>Delvotest SP/Delvotest SP Mini</b>	<p><i>Charm B. stearothermophilus</i> Tablet Disk Assay  Charm II Tablet Beta-lactam Test (Competitive Assay)  Charm II Tablet Beta-lactam Test (Sequential Assay)  Charm I/Cowside II Tablet Beta-lactam Test  Charm II Tablet Beta-lactam Test (Quantitative Assay)  Charm SL Beta-lactam Test  Delvotest P 5 Pack  Delvotest P/Delvotest P Mini  Delvotest SP/Delvotest SP Mini  Delvo-X-Press Beta-lactam Residue Test Kit  Penzyme III Test Procedure  Penzyme Milk Test  SNAP Beta-lactam Test Kit  Parallux Beta-lactam Assay</p>
<b>Delvo-X-Press Beta-lactam Residue Test Kit</b>	<p><i>Charm B. stearothermophilus</i> Tablet Disk Assay + Lactek CEF Beta-lactam Milk Screening Kit  Charm II Tablet Beta-lactam Test (Competitive Assay)  Charm II Tablet Beta-lactam Test (Sequential Assay)  Charm I/Cowside II Tablet Beta-lactam Test  Charm II Tablet Beta-lactam Test (Quantitative Assay)  Charm SL Beta-lactam Test  Delvotest P 5 Pack + Lactek CEF Beta-lactam Milk Screening Kit  Delvotest P/Delvotest P Mini + Lactek CEF Beta-lactam Milk Screening Kit  Delvotest SP/Delvotest SP Mini + Lactek CEF Beta-lactam Milk Screening Kit  Delvo-X-Press Beta-lactam Residue Test Kit  Penzyme III Test Procedure + Lactek CEF Beta-lactam Milk Screening Kit  Penzyme Milk Test + Lactek CEF Beta-lactam Milk Screening Kit  SNAP Beta-lactam Test Kit  Parallux Beta-lactam Assay</p>

<b>Lactek B-L Beta-lactam Milk Screening Kit</b>	Charm B. stearothermophilus Tablet Disk Assay + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Charm II Tablet Beta-lactam Test (Competitive Assay) + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Charm II Tablet Beta-lactam Test (Sequential Assay) + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Charm I/Cowside II Tablet Beta-lactam Test + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm SL Beta-lactam Test + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Delvotest P 5 Pack + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Delvotest P/Delvotest P Mini + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Delvotest SP/Delvotest SP Mini + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Delvo-X-Press Beta-lactam Residue Test Kit + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Lactek B-L Beta-lactam Milk Screening Kit Penzyme III Test Procedure + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Penzyme Milk Test + Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk SNAP Beta lactam Test Ki t+ Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk Parallux Beta-lactam Assay
<b>Lactek CEF Beta-lactam Milk Screening Kit</b>	Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm II Tablet Beta-lactam Test (Quantitative

	<p>Assay)</p> <p>Charm SL Beta-lactam Test</p> <p>Delvo-X-Press Beta-lactam Residue Test Kit</p> <p>Lactek CEF Beta-lactam Milk Screening Kit</p> <p>SNAP Beta-lactam Test Kit</p> <p>Parallux Beta-lactam Assay</p> <p>Parallux Ceftiofur Assay</p>
<b>Penzyme III Test Procedure</b>	<p>Charm B. stearothermophilus Tablet Disk Assay</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test</p> <p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm SL Beta-lactam Test</p> <p>Delvotest P 5 Pack</p> <p>Delvotest P/Delvotest P Mini</p> <p>Delvotest SP/Delvotest SP Mini</p> <p>Delvo-X-Press Beta-lactam Residue Test Kit</p> <p>Penzyme III Test Procedure</p> <p>Penzyme Milk Test</p> <p>SNAP Beta-lactam Test Kit</p> <p>Parallux Beta-lactam Assay</p>
<b>Penzyme Milk Test</b>	<p>Charm B. stearothermophilus Tablet Disk Assay</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test</p> <p>Charm II Tablet Beta-lactam Test (Quantitative Assay)</p> <p>Charm SL Beta-lactam Test</p> <p>Delvotest P 5 Pack</p> <p>Delvotest P/Delvotest P Mini</p> <p>Delvotest SP/Delvotest SP Mini</p> <p>Delvo-X-Press Beta-lactam Residue Test Kit</p> <p>Penzyme III Test Procedure</p> <p>Penzyme Milk Test</p> <p>Parallux Beta-lactam Assay</p>
<b>SNAP Beta-lactam Test Kit</b>	<p>Charm B. stearothermophilus Tablet Disk Assay + Lactek CEF Beta-lactam Milk Screening Kit</p> <p>Charm II Tablet Beta-lactam Test (Competitive Assay)</p> <p>Charm II Tablet Beta-lactam Test (Sequential Assay)</p>

	Charm I/Cowside II Tablet Beta-lactam Test Charm II Tablet Beta-lactam Test (Quantitative Assay) Charm SL Beta-lactam Test Delvotest P 5 Pack + Lactek CEF Beta-lactam Milk Screening Kit Delvotest P/Delvotest P Mini + Lactek CEF Beta-lactam Milk Screening Kit Delvotest SP/Delvotest SP Mini + Lactek CEF Beta-lactam Milk Screening Kit Delvo-X-Press Beta-lactam Residue Test Kit SNAP Beta-lactam Test Kit Parallux Beta-lactam Assay
--	---

## INFORMATION TO BE USED WITH THE PARALLUX BETA-LACTAM ASSAYS

The Parallux Beta-lactam Assay consists of **four separate tests** performed on four different channels at the same time. When **only** one of the channels indicates positive with the tanker milk, then the producer's sample may be confirmed with the tests listed below the corresponding positive on a single channel.

If more than one channel indicates positive with the tanker milk, then each producer's sample must be confirmed with separate tests corresponding to all of the positive channels. The Parallux Beta-lactam Assay may be used to confirm the producer's sample for the presence of one or more positive channels, to include up to four separate positive channels, at the same time.

INITIAL POSITIVE TEST	CONFIRMATORY TEST OPTIONS
<b>Positive only on the <u>ceft</u> channel in the <u>Beta-lactam</u> cartridge</b>	Parallux Beta-lactam Assay Parallux Ceftiofur Assay SNAP Beta-lactam Lactek CEF Beta-lactam Milk Screening Kit Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm SL Beta-lactam Test Delvo-X-Press Beta-lactam Residue Test
<b>Positive only on the <u>clox</u> channel in the <u>Beta-lactam</u></b>	Parallux Cloxacillin Assay Parallux Beta-lactam Assay

<b>cartridge</b>	Charm I/Cowside Test for Cloxacillin in Milk (Competitive Assay) Charm II Test for Cloxacillin in Milk (Competitive Assay) Lactek B-L Beta-lactam Milk Screening Kit
<b>Positive only on the <u>pen</u> channel in the <u>Beta-lactam</u> cartridge</b>	Parallux Cillins Assay Parallux Beta-lactam Assay SNAP Beta-lactam Lactek B-L Beta-lactam Milk Screening Kit Charm B. Stearothermophilus Tablet Disk Assay Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm SL Beta-lactam Test Delvotest P 5 Pack Delvotest P/Delvo Test P Mini Delvotest SP/Delvo Test SP Mini Delvo-X-Press Beta-lactam Residue Test Penzyme Milk Test Penzyme III Test Procedure
<b>Positive only on the <u>ceph</u> channel in the <u>Beta-lactam</u> cartridge or in the <u>2X</u> cartridge.</b>	Parallux Cephapirin Assay Parallux Beta-lactam Assay SNAP Beta-lactam Charm B. Stearothermophilus Tablet Disk Assay Charm II Tablet Beta-lactam Test (Competitive Assay) Charm II Tablet Beta-lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta-lactam Test Charm SL Beta-lactam Test Delvotest P 5 Pack Delvotest P/Delvo Test P Mini Delvotest SP/Delvo Test SP Mini Delvo-X-Press Beta-lactam Residue Test Penzyme Milk Test Penzyme III Test Procedure
<b>Positive only on the <u>pen</u> channel in the <u>2X</u> cartridge*</b>	Parallux Beta-lactam Assay Charm B. Stearothermophilus Tablet Disk Assay and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm SL Beta-Lactam Test (Sequential Assay) and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)

	<p>Charm II Tablet Beta-Lactam Test (Competitive Assay) and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Charm I/Cowside II Tablet Beta-lactam Test and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Delvotest P 5 Pack and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Delvotest P/Delvo Test P Mini and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Delvotest SP/Delvo Test SP Mini and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Delvo-X-Press Beta-lactam Residue Test and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Penzyme Milk Test and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>Penzyme III Test Procedure and Charm I/Cowside II Test for Cloxacillin in Milk or Charm II Test for Cloxacillin in Milk (Competitive Assay)</p> <p>SNAP Beta-lactam and Charm II Test for Cloxacillin in Milk (Competitive Assay)</p>
--	--

\* Since the **pen** (Penicillin Channel) is uniquely sensitive to cloxacillin, both the **pen** channel and the **clox** channel will respond to the presence of Cloxacillin in a milk sample to give a dual presumptive positive response. Positive only on the **pen** channel in the **2X cartridge** requires a retest for all four antibiotics: penicillin, ampicillin, amoxicillin **and cloxacillin**.